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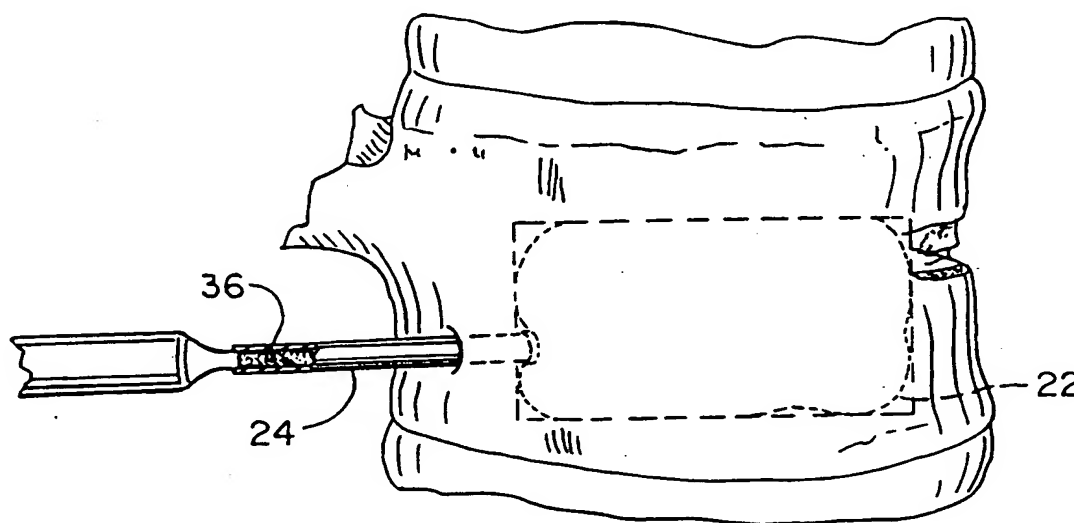
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(54) Title: METHOD AND APPARATUS FOR TREATING A VERTEBRAL BODY



(57) Abstract: An implantable container (22) inserted between vertebrae in order to stabilize or restore height to the vertebral body. The container is then filled with bone filler materials (36) to expand the device into a fixed shape which conforms to the cavity shape. The container may be a porous membrane with holes (44) or an inelastic nonporous membrane.

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Method and Apparatus for Treating a Vertebral Body

Cross-reference to related cases

5 The present case claims the benefit of the following Provisional Applications: "Cavity Sealing Barrier", serial number 60/185,323, filed 2/28/2000 ; "Implant for Hard Bones", serial number 60/220,303, filed 7/24/2000 ; "Vertebral Body Sealing Device and Method", serial number 60/239,216, filed 10/10/2000; "Hydraulic Distraction with Permeable
10 Membrane", serial number 60/239,217 , filed 10/10/2000.

Field of the Invention

 The present invention relates generally to the treatment of bones and more particularly to the treatment of the vertebral bodies found in the
15 human spine.

Background of the Invention

 The human spine consists of a complex set of interrelated anatomic elements including a set of bones called vertebral bodies. Intervertebral
20 discs separate most vertebral bodies. These discs includes a "spongy" nucleus pulposus surrounded by an annulus fibrosis "membrane". The annulus fibrosis connects the opposed endplates of adjacent vertebral bodies. All of these structures together with muscles act to provide motion, stability and protection for the spine. When healthy, these structures
25 effectively protect the spinal cord and allow for normal motion.

 However there are many disease states and aging processes that impact the patient. Osteoporosis and metastatic disease reduce the structural integrity of the vertebral bodies, predisposing them to fracture. Vertebral fractures can lead to loss of vertebral height which can exacerbate
30 existing neurological condition or it can predispose the spine to other symptoms. Back pain often results from these conditions. Vertebroplasty is an effort to stabilize these fractures and to alleviate this source of pain.

Generally, fractures and loss of height if not treated results in a cascade of injury which is undesirable. For this reason various efforts have been directed at stabilizing and restoring the natural vertebral bodies of the back. Efforts have also been directed to replacing the vertebral bodies.

5 US Patent 5,108,404 to Scholten et al among others teaches a technique for height restoration that uses a bone cement product introduced into a cavity after a cavity has been made with an inflatable device. One problem with this system is the extravasation of bone cement to sensitive areas. Another problem is the difficulty of obtaining consistent control of
10 height restoration with the Scholten system.

Summary

In contrast to the prior art, the present invention involves both a container device that is permanently implanted and a method of using the container to stabilize the vertebral body or to restore height to the vertebral
15 body.

In one embodiment the container is porous to the bone filler material. In another embodiment the container is impermeable to the bone filler material. In each embodiment the container controls and regulates the delivery of bone filler material into the vertebral body.

20 In one embodiment the container is flexible and conformal to the cavity. In another embodiment the container has a fixed shape which conforms to the cavity shape when deployed.

In one embodiment of the method, the bone filler is injected until the cavity is completely filled stabilizing the vertebral body. In another
25 embodiment of the method the bone filler is injected and displaces the endplates of the vertebral body "restoring height" through a hydraulic jacking effect and stabilizing their vertebral body.

There are numerous bone filler materials which can be used to fill the container including bone cement and other materials. However it is a
30 general property of the bone fillers that they must be injectable in a fluid state and that they harden.

Brief Description of the Drawings

Throughout the several views of the drawings there are shown illustrative embodiments of the inventions in which like reference numerals indicate equivalent or identical structure, wherein:

Fig. 1 is a sectional view of a vertebral body;

5 Fig. 2 is a view of a vertebral body in elevation;

Fig. 3 is a view of a vertebral body in elevation;

Fig. 4 is a view of a vertebral body with items shown in phantom view;

10 Fig. 5 is a view of a vertebral body with items shown in phantom view

Fig. 6 is a view of a vertebral body with items shown in phantom view

Fig. 7 is a view of a vertebral body with items shown in phantom view

15 Fig. 8 is a view of a vertebral body with items shown in phantom view

Fig. 9 is a view of a vertebral body with items shown in phantom view

20 Fig. 10 is a view of a vertebral body with items shown in phantom view;

Fig. 11 is a view of a vertebral body with items shown in phantom view;

Fig. 12 is a view of an embodiment of a porous container in use;

Fig. 13 is a view of an embodiment of a porous container;

25 Fig. 14 is a view of a porous container in a cutaway vertebral body;

Fig. 15 is a view of a container in isolation;

Fig. 16 is a view of a container in isolation;

Fig. 17 is a perspective view of a container in a vertebral body;

Fig. 18 is a perspective view of a container in a vertebral body;

30 Fig. 19 is a perspective view of a container in a vertebral body;

Fig. 20 is a perspective view of a container in a vertebral body;

Fig. 21 is a perspective view of a container in a vertebral body

Fig. 22 is a perspective view of a container in a vertebral body

Throughout the several views of the drawings there are shown illustrative embodiments of the inventions in which like reference numerals indicate equivalent or identical structure, wherein:

Fig. 1 is a sectional view of a vertebral body;

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25 Fig. 14 is a view of a porous container in a cutaway vertebral body;

Fig. 15 is a view of a container in isolation;

Fig. 16 is a view of a container in isolation;

Fig. 17 is a perspective view of a container in a vertebral body;

Fig. 18 is a perspective view of a container in a vertebral body;

30 Fig. 19 is a perspective view of a container in a vertebral body;

Fig. 20 is a perspective view of a container in a vertebral body;

Fig. 21 is a perspective view of a container in a vertebral body

Fig. 22 is a perspective view of a container in a vertebral body

Fig. 23 is a view of a tubular container;

Fig. 24 is a view of a tubular container in use;

Fig. 25 is a view of a fill tube construction;

Fig. 26 is a view of a fill tube construction;

5 Fig. 27 is a view of a fill tube construction; and,

Fig. 28 is a view of an alternate porous container embodiment.

Detailed Description

The various container devices and the methods for using the
10 container devices are disclosed in the context of the treatment of vertebral
bodies. It should be recognized that the inventions may be used in other
bones which present the same or similar pathologies, including but not
limited to tibial plateaus, distal radius fractures, calcaneous fractures.

Fig. 1, Fig. 2 and Fig. 3 taken together are intended to show a cavity
15 creation process that precedes treatment with the devices and methods of
the invention. In general cavity creation techniques are well known and
they may include the creation of a cavity with a balloon device as is known
in the art.

Fig. 1 shows a vertebral body 10 in partial cross section. The exterior
20 portion of the vertebra is dense cortical bone and the interior is porous
cancellous bone which is labeled 12 in the figure. The cavity 14 is depicted
by the dashed outline in the drawing and it is formed in the porous bone.
The shape of the cavity depends on the technique used to form it. This
cavity is made in a conventional way. For example a tool may be
25 introduced through extra-pedicular access tube 16 or transpedicular access
tube 18 and operated in the vertebral body. As seen in the drawing the
extrapedicular access tube 16 may have a larger diameter and will be
preferred by some surgeons. In general, the access approach for cavity
creation will also be used for the introduction of the devices of the
30 invention. These approaches will be used for the methods of the invention.

Fig. 2 shows a collapsed vertebral body 10 in elevation with a
compression fracture and associated loss of height. The superior endplate
20 has moved due to a fracture and normal loading. The nominal height of

the cavity formed in this vertebral body is labeled "h1" in the figure. As the end plate moves the angle formed between the superior endplate 20 and the inferior endplate 21 becomes acute which is undesirable. In the extreme case both sides of the endplates fall to form a severely compressed rectangular shaped vertebral body.

Fig. 3 shows a fractured vertebral body that requires intervention. In this vertebral body the height of the cavity 14 is indicated by the nominal height of the vertebral body labeled as "h2" in the figure.

Taken together the Figures 1, 2 and 3 represent the formation of a cavity 14 prior to treatment with device of the present invention.

Taken together Fig. 4 Fig. 5 and Fig. 6 represent steps in a method to stabilize a fractured vertebral body.

Fig. 4 shows a step in the method. In this drawing the container 22 is coupled to a fill tube 24 shown in phantom view. In this embodiment the container 22 is located at the distal end of a fill tube 24. The container 22 and fill tube 24 are carried together with the delivery tube 26. The motion arrow 28 indicates that the delivery tube 26 and fill tube 24 are being moved together into the surgically prepared cavity 14. The delivery tube 26 may be the same device that is used to deliver the cavity tools as discussed with reference to Fig. 1. Or the tube 26 may be a separate device inserted through an alternate access aperture.

Fig. 5 shows the deployment process step where the delivery tube 26 is retracted as indicated by motion arrow 30 while the fill tube 24 and the attached container 22 remain stationary in the vertebral body 10 cavity 14.

Fig. 6 shows the expansion of the container 22 within the cavity 14. The bone filler material 36 seen in phantom view has been loaded into the manually operated syringe 32 and the physician is injecting the material through the fill tube 24 into the container 22. The container 22 has unfurled and conformed to the shape of the cavity 14. The unconstrained shape of this container is generally cylindrical with spherical ends. This figure shows the deployment of the container in to a cavity which is substantially the same volume as the cavity 14. In this illustrative example the volume of the

container is larger than the volume of the cavity and there is no stretching force applied to the impermeable container membrane.

The coupling 34 between the fill tube and the syringe 32 may be a conventional luer lock or other attachment device. Although a syringe is an effective filler delivery tool it is expected that physicians will use an alternative delivery system such as a an extruder rod inserted directly into the fill tube to displace bone filler into the container.

Fig. 7 depicts the preliminary preparation of a cavity 14 in a collapsed vertebral body 10.

Fig. 8 shows an introduction step in the hydraulic jacking process. In this illustration the container 22 and its attached fill tube 24 are inserted into the vertebral body 10 together with the delivery tube 26. The assembly is positioned in the cavity 14 proximate the end of the cavity. In this step care must be taken to prevent pressurizing the device within the pedicle.

Fig. 9 shows a deployment step in the process. In this illustration the container is fully deployed in the cavity 14 by withdrawing the delivery tube (not shown) from the fill tube leaving the container 22 exposed in the cavity 14.

Fig. 10 shows an injection step in the process. The container 22 is filled through the fill tube 24 with a bone filler materials 36. The manual syringe 32 or other injection device injects the material at a sufficient pressure to create distraction forces shown in the figure a superior force 40 and inferior force 42. These forces are sufficient to move the endplate 20 and end plate 21 apart restoring height and angulation.

Fig. 11 shows a step of the process where an end point of the method is reached. Here the container 22 is completely filled and the original height of the vertebral body is restored. This end point can be determined in any of several ways. For example an inelastic fixed volume container can be used and the injecting process stopped when resistance is felt through the hydraulic connection with the container. An alternate approach is the injection of a fixed volume of bone filler into an oversized elastic or porous container 22. Also the physician may follow the injection under fluoroscopy and limit injection through observation of a real time image in combination

with medical judgement. In this instance the container can be inelastic or elastic. The final step in the typical method will be to remove the fill tube 24 from the container 22. This step will typically be performed after the bone filler 36 material is "step up" and no longer in a low viscosity state.

5 These initial figures depict the stabilization method and the hydraulic jacking method performed with substantially cylindrical containers. The membranes in the examples have all been impermeable to the bone filler. In these process the container may be elastic or inelastic as may be desired by the physician.

10 The stabilization method may be performed with all of the container devices shown.

 The hydraulic jacking method can be performed with the all of the container devices with the exception of Fig. 13 and Fig. 14.

15 Fig. 12 shows an alternate container 22 with a membrane perforated by a series of holes typified by hole 44. When placed in a vertebral body the bone filler 36 extrudes from the holes and interdigitates with the cancellous bone 12 inside the vertebral body 10. It is difficult to illustrate this process but the cavity 14 has a wall that is porous so the bone filler interdigitates with the cancellous bone matrix.

20 Fig. 13 shows a tubular fixed diameter form of the container 22 which can be used to control the delivery of bone filler to the cavity. The container 22 approximates the size and shape of the cavity, prior to bone filler injection. The holes in the device distribute the bone filler to locations next to the holes.

25 Fig. 14 shows the container of Fig. 13 in operation in a vertebral body 10.

 One preferred method of use which can be performed with porous containers involves the injection of a first volume of relatively less viscous bone filler to promote interdigitation of the cancellous bone. Next a second
30 injection of bone filler material with a different mechanical strength or chemical composition is injected and it "pushes" against the initial or primary injected material. This technique produces a gradient of strength and elasticity through the repaired bone which mimics the mechanical

characteristics of the natural bone. The relatively small diameter of this device allow the set of apertures to distribute the various bone filler materials without moving the device during injection.

Another preferred method involves the same two stage injection process with a non-porous or impermeable container. In this instance there is negligible interdigitation but the gradient remains.

Fig. 15 is a container with an asymmetrical distribution of holes so that the extrusion of bone filler occurs on one side of the container. This construction may allow the container to be moved within the vertebral body during injection of bone filler.

Fig. 16 shows an asymmetrical container 22 where hole size and distribution vary over the surface of the membrane. For example hole 44 is larger than holes 45 which lie along the axis of the fill tube 24. This asymmetry provides physician control of the distribution and the flow of the bone filler materials into specific regions of the vertebral body.

Fig. 17, Fig. 18 and Fig. 19 should be considered together. This group of drawings depicts an alternate "horseshoe" shape for the construction for the container 22. In each instance the fill tube has been eliminated from the figure to improve clarity. However it should be understood that at least one fill tube is used with each container in these figures. All of the container devices depicted in Fig. 17 through Fig. 20 can be made of porous or non-porous membrane materials.

Fig. 17 is single chamber fixed volume device 22 which may expand to a nominal height in the vertebral body 10.

Fig. 18 is a segmented horseshoe shaped container 22 device with a horizontal rib 70 that divides the container into two separate structures. The inner of the membrane 71 may be continuous with this rib 70 or weep holes may be provided to facilitate flow of bone filler within the device. The exterior surface of the membrane 73 may be porous or impermeable to bone filler. In this embodiment the rib 70 will effectively limit the height achieved in the vertebral body.

Fig. 19 is multi-chambered device with several lateral compartments created by ribs typified by rib 74. In this embodiment the chambers typified

by chamber 75 limit the horizontal extent of the growth of the container during the hydraulic jacking process.

Fig. 20 is single chamber fixed volume device 22 with a triangular "footprint".

5 Fig. 21 is a segmented triangular device with a horizontal rib 76 defining two chambers.

Fig. 22 is multi-chambered device with several lateral compartments created by ribs typified by rib 77.

Fig. 23 shows an alternate tubular embodiment of a single chamber
10 container 22 with a stylet 92 coupled to the most distal end of the container 22. This elongate tubular container is deployed by advancing the stylet 92 wire out of the delivery tube, which drags the container membrane out of the delivery tube 26 or the fill tube 24. In this device the container may be
15 folded and placed entirely everted in the fill tube. This construction will thereby maximizing the inner diameter of the fill tube.

Fig. 24 shows the alternate tubular embodiment of the container in its partially filled configuration. In this illustration the vertebral body 10 has had an oval cavity 14 formed in the cancellous bone. The stylet 92 is used to
20 force the container 22 along the outer wall path of the cavity 14 and it is then removed. Next bone filler material is injected through the fill tube and the annular ring tubular container is filled.

Fig. 25 shows a simple slip fit between the fill tube 24 and a complementary structure on the container 22. In this construction a septum
25 82 is used to fill the container 22 through a fill needle 84. One advantage of this construction is the septum seals the container and allows the container to seal while the bone filler hardens.

Fig. 26 shows an area or zone of weakness 83 in the fill tube 24 that preferentially breaks off to remove the fill tube from the container.

30 Fig. 27 the toothed member 85 circulates around the axis of the fill tube 24 and cuts off the fill tube away from the container after the bone filler has hardened.

Fig. 28 shows the container formed as a porous woven membrane 90. In use the bone filler 36 will exude from the area between the woven fibers to permeate the cancellous bone. The woven mesh will produce the same effect as an elastic membrane.

5 Various materials may be used to make the container including , polyethylene Teflon, Gore-Tex, polybutylene terephthalate, polyethylene terephthalate glycol, urethane and urethane coated materials. The material or the construction can give rise to elastic or inelastic structures both of which are operable in the methods of the invention. The woven
10 embodiments of the porous container may also be made from metal meshes or screens including titanium, elgiloy MP35 nitinol, stainless steel, or other bio-compatible metals.

Various bone fillers contemplated within the scope of this invention. Bone fillers are defined for this disclosure as any substance used to stabilize
15 the bone and includes but is not limited to bone cement, human bone graft (allograft autograft), synthetic derived bone substitutes such as calcium phosphate and hydroxylapatite. Bone fillers may be supplemented with other biologically active materials including but not limited to collagen osteoinductive agents including bone morphogenic proteins. Other known
20 ceramic based materials can be used as well. Other known bioresorbable polymers may be used as well.

Illustrative embodiments of the invention have been shown but numerous modifications may be made without departing from the scope of the invention which is defined by the appended claims.

25

What is claimed is:

1. An implantable device for insertion into a cavity in a vertebral body comprising:
 - 5 a flexible container having a wall membrane:
 said wall membrane defining an interior and an exterior of said container;
 said wall having at least one hole connecting the interior with the exterior;
 - 10 a fill tube coupled to said container at a location proximate an edge of said container for injecting a flowable or fluid bone filler material into said container such that said bone filler leaves said interior and enters said vertebral body.
- 15 2. The device of claim 1 wherein said container is substantially tubular in shape.
3. The device of claim 1 wherein said wall membrane is elastic.
- 20 4. The device of claim 1 wherein said wall membrane is inelastic.
5. The device of claim 1 wherein at least one of said wall membranes is woven.
- 25 6. The device of claim 1 wherein said wall membrane is porous.
7. The device of claim 1 wherein said wall membrane is not porous.
8. The device of claim 1 further comprising:
 - 30 a septum located adjacent said container and in fluid communication with said interior for permitting the sealing entry of a filling device.

9. The device of claim 1 wherein said membrane is opaque to x-ray and is therefore radiopaque.

10. The device of claim 1 wherein said membrane is transparent to x-rays
5 and is therefore radio-translucent.

11. The device of claim 1 further comprising a delivery tube, wherein said container is everted within said delivery tube.

10 12. An implantable device for insertion into a cavity in a vertebral body comprising:

a container including;

an upper wall member;

a lower wall member;

15 a circumferential wall member;

a set of ribs extending from said upper wall to said lower wall, thereby forming a set of channels.

13. The device of claim 12 wherein said upper and lower wall member have
20 a substantially horseshoe shape.

14 The device of claim 12 wherein said upper and lower wall member have a substantially triangular shape.

25 15. The device of claim 12 wherein said container is substantially cylindrical in shape.

16. The device of claim 12 wherein said wall membrane is elastic.

30 17. The device of claim 12 wherein said wall membrane is inelastic.

18. The device of claim 12 wherein at least one of said wall membranes is woven.

19. The device of claim 12 wherein said wall membrane is porous.

20. A method of treating an vertebral body having a superior endplate and
5 an inferior endplate, comprising the steps of:
 inserting a container into an vertebral body;
 deploying said container within said vertebral body;
 injecting a bone filler material into said container under pressure;
 whereby said pressure supplies a distraction force to move
10 said superior and inferior endplates apart;
 ending injection after said endplates have moved apart.

21. The method of claim 20 wherein said filler material is selected from the
group comprising:
15 bone cement, human bone graft allograft; human bone graft
autograft; synthetic derived bone substitute; sulfate and/or calcium
phosphate, hydroxylapatite.

22. A method of treating an vertebral body comprising the steps of:
20 creating a cavity in the vertebral body through an access aperture;
 inserting a container into said vertebral body;
 said container having a fill passage coupled to said container;
 deploying said container within said vertebral body;
 injecting a bone filler material into said container through said fill
25 passage.

23. A method of treating an vertebral body comprising the steps of:
 inserting a container into an vertebral body;
30 said container having a fill passage coupled to said container;
 said container having a porous outer membrane sufficiently
porous to allow filler material under pressure to leave the container
after filling the container;

deploying said container within said vertebral body

injecting a filler material into said container through said fill passage
with bone filler material in a sufficient volume to allow the bone filler

material to exit the container and interdigitates with cancellous bone within

5 said vertebral body thereby reinforcing said bone and stabilizing fractures
in said bone;

said container membrane porosity sufficient to provide resistance to
the flow of said bone filler material to generate force to move the endplates
of said vertebral body.

10

24. The method of claim 23 wherein said injecting step is ended after the
superior and inferior endplates move toward a normal anatomic position.

25. An implantable device for insertion into a cavity in a vertebral body

15 comprising:

a container including;

an upper wall member;

a lower wall member;

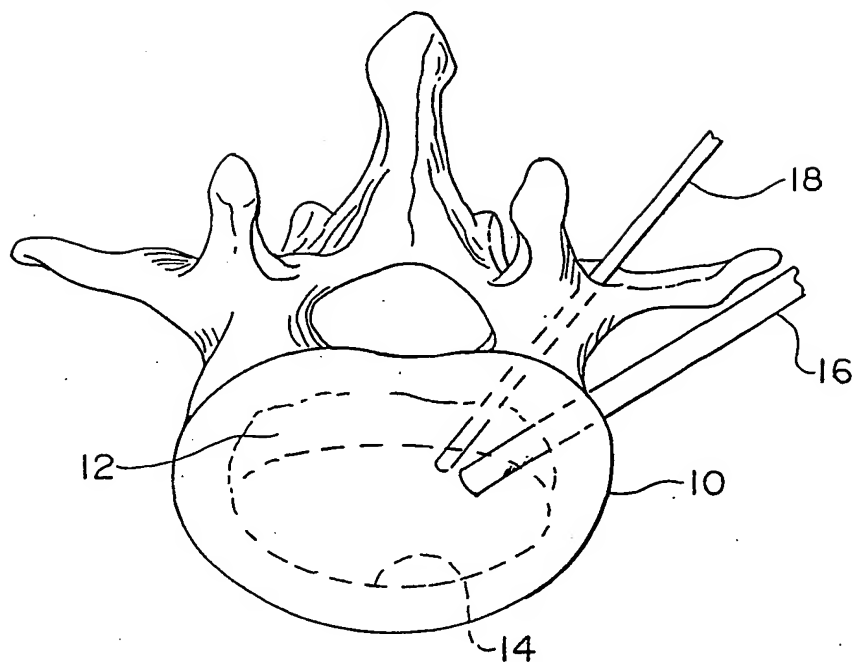
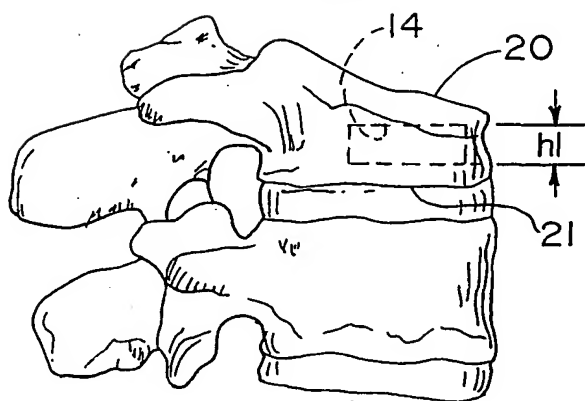
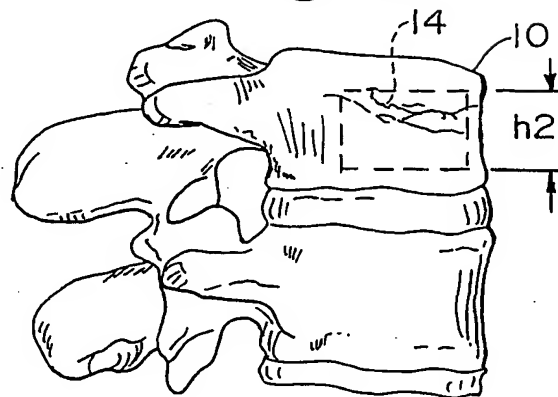
a circumferential wall member;

20 said wall members together defining a single chamber.

26. The device of claim 25 wherein said upper and lower wall member have
a substantially horseshoe shape.

25 27. The device of claim 25 wherein said upper and lower wall member have
a substantially triangular shape.

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Fig. 1**Fig. 2****Fig. 3**

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Fig. 4

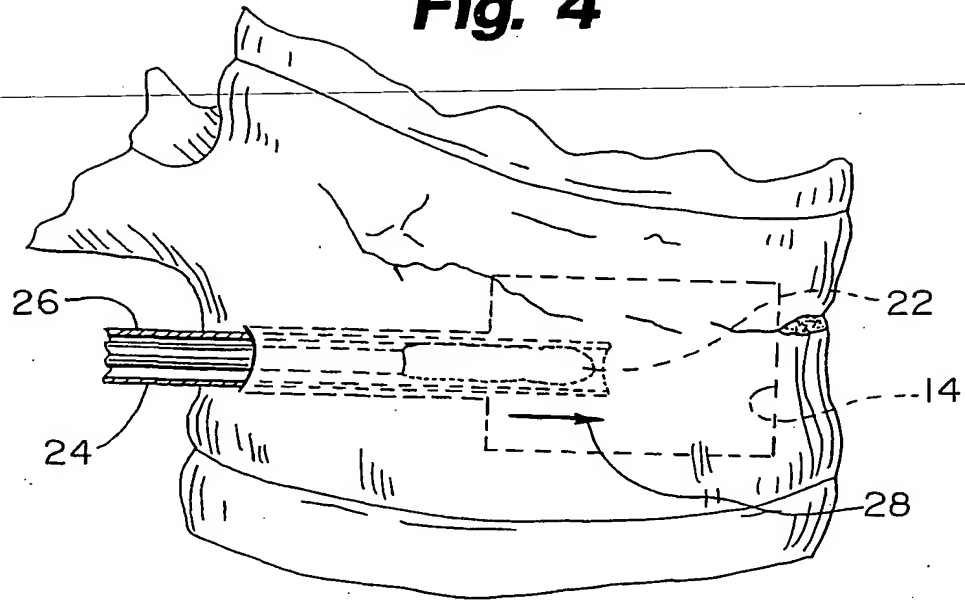
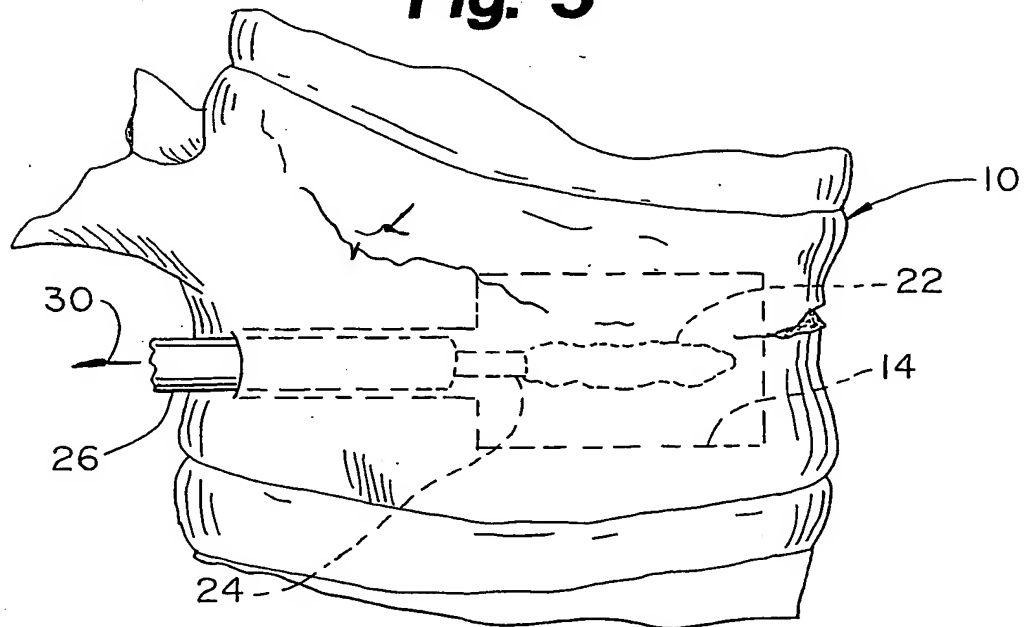
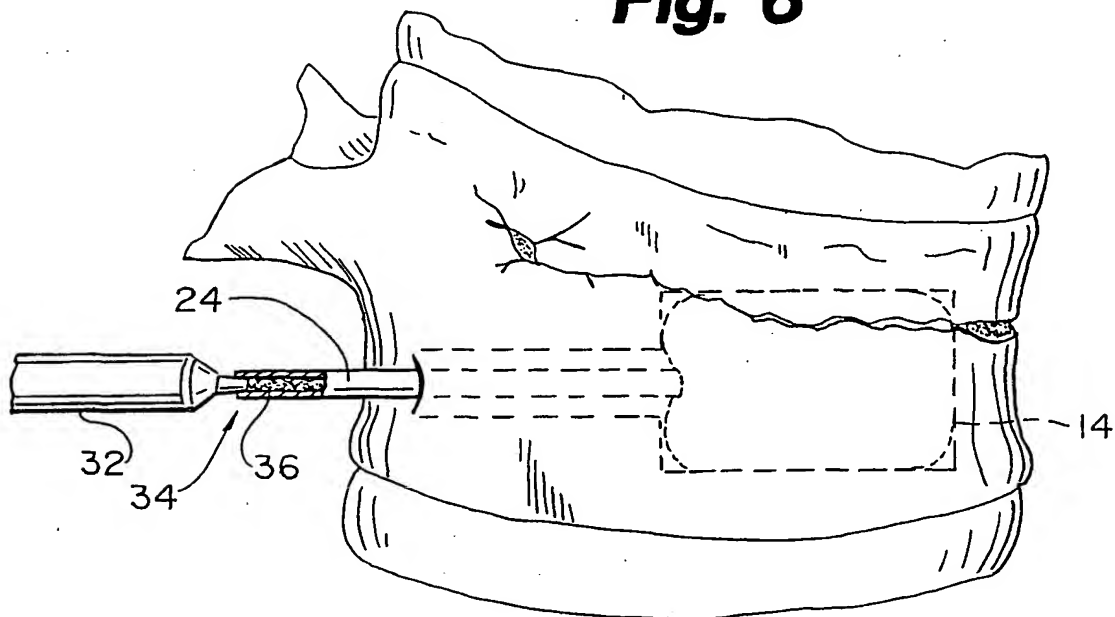
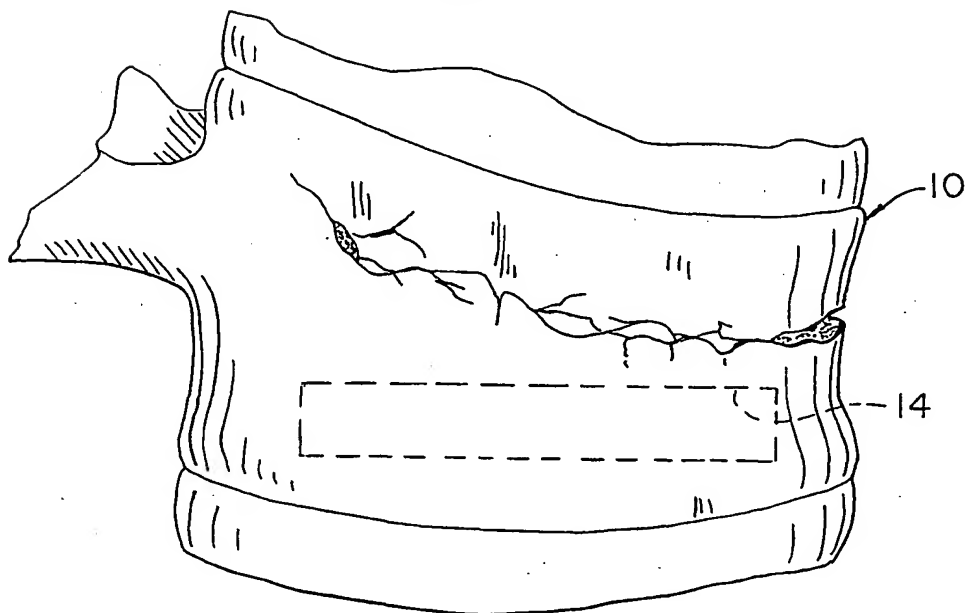


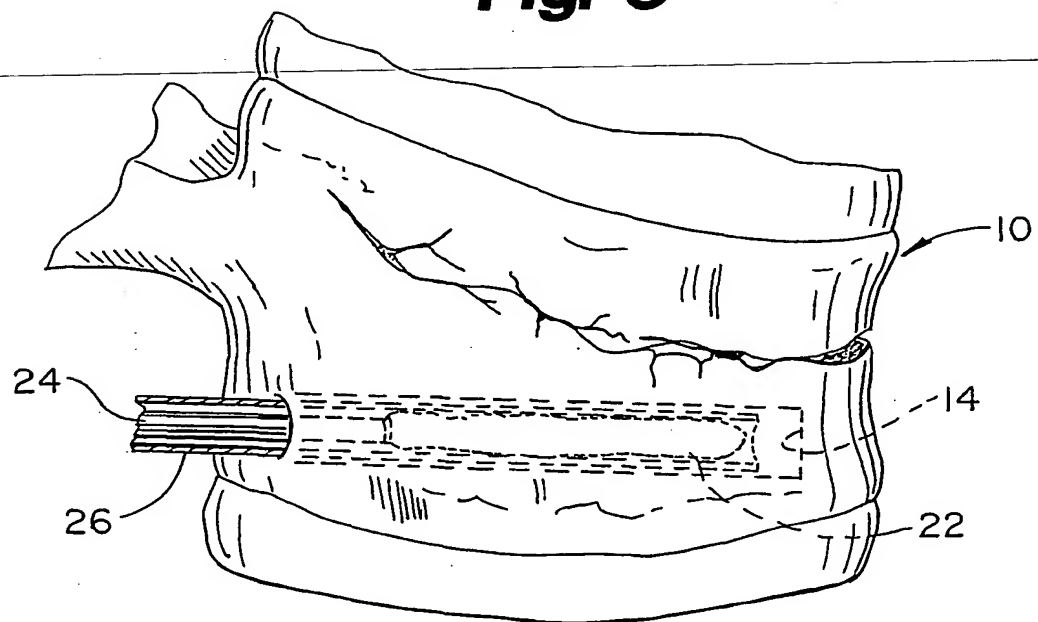
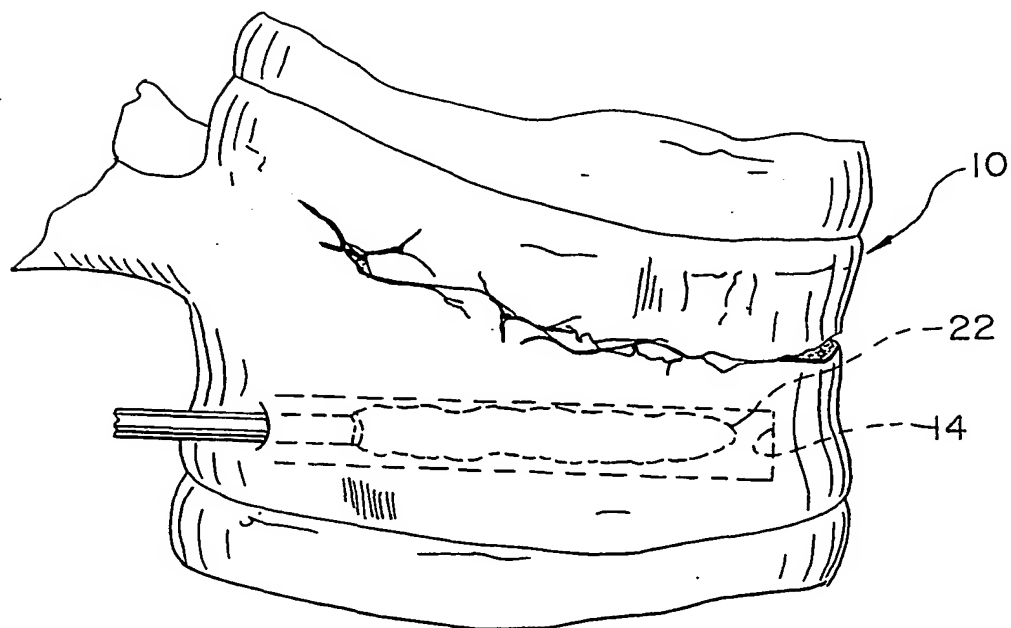
Fig. 5



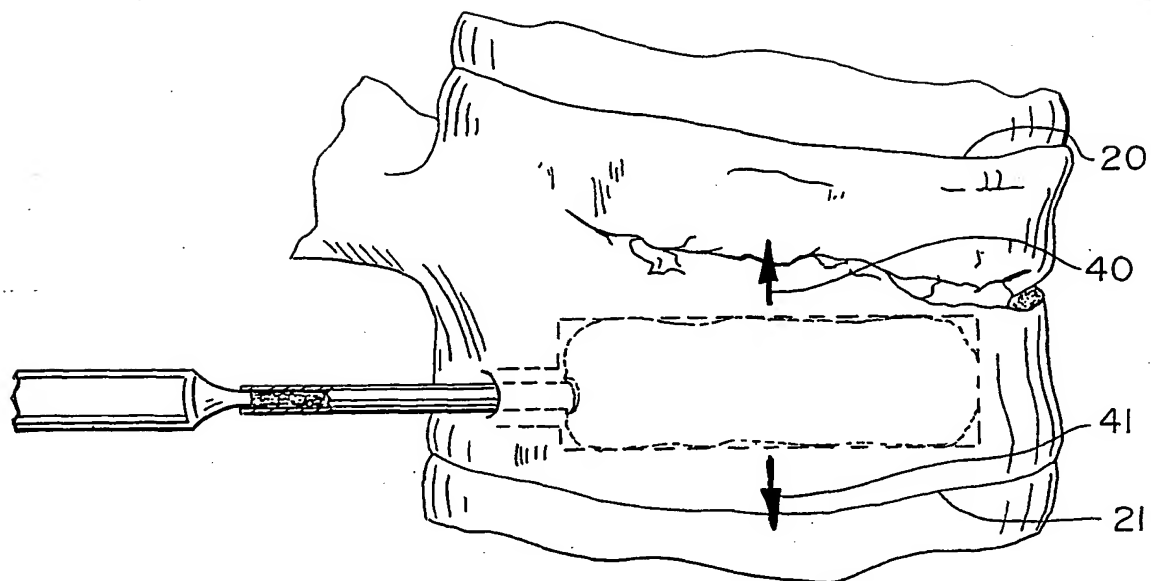
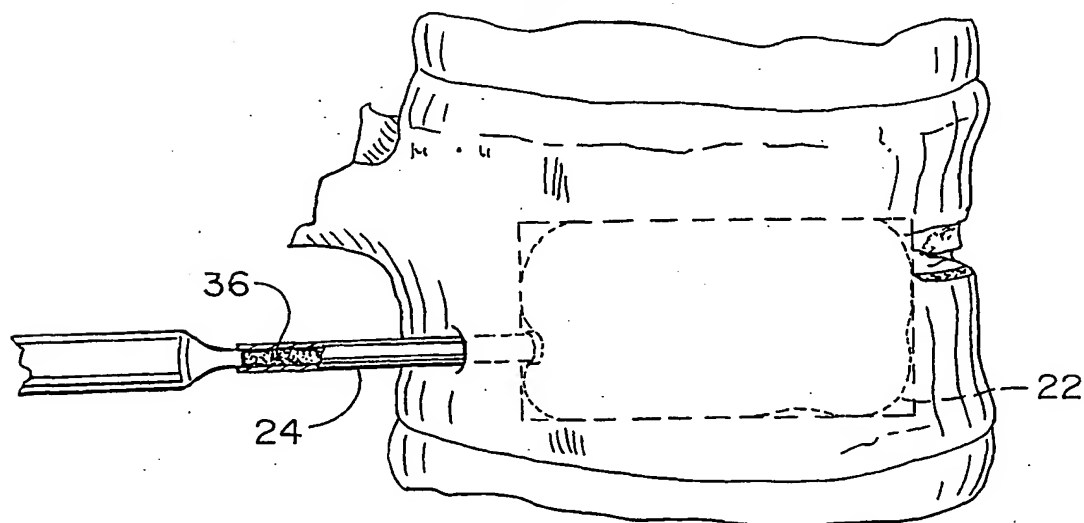
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Fig. 6**Fig. 7**

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Fig. 8**Fig. 9**

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Fig. 10**Fig. 11**

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Fig. 12

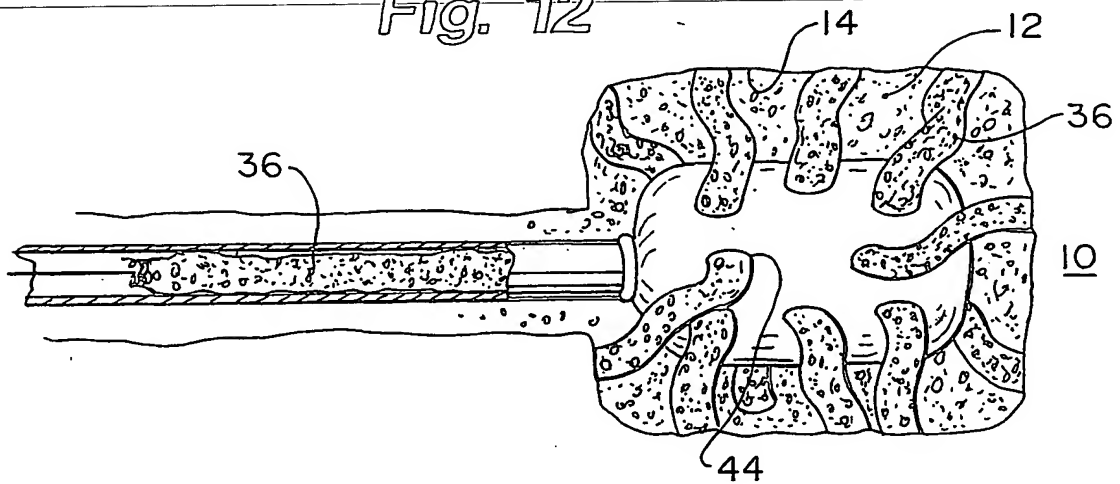
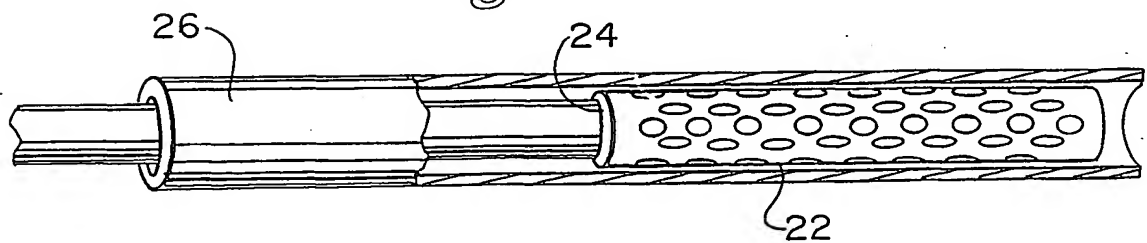
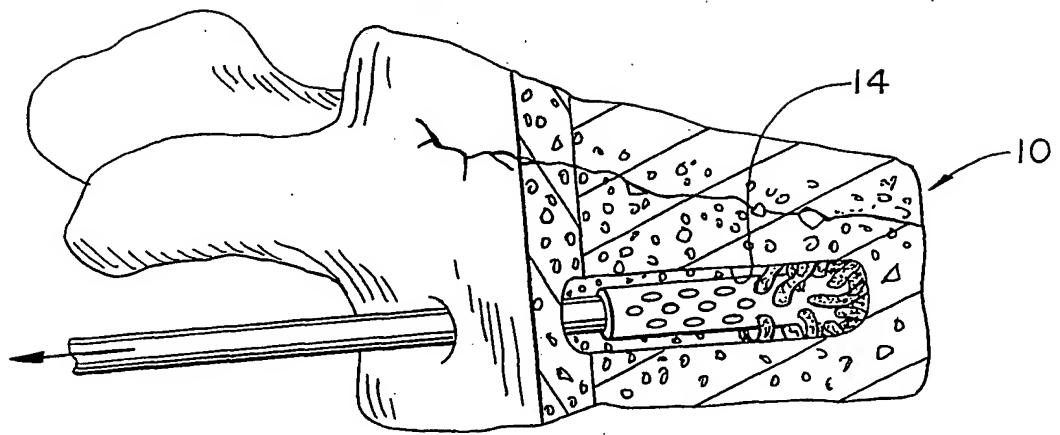
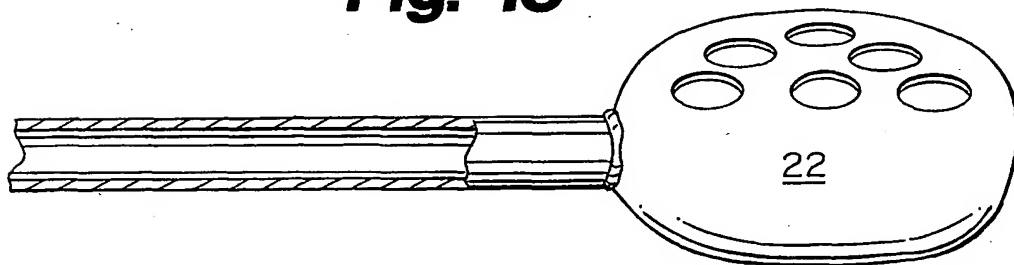
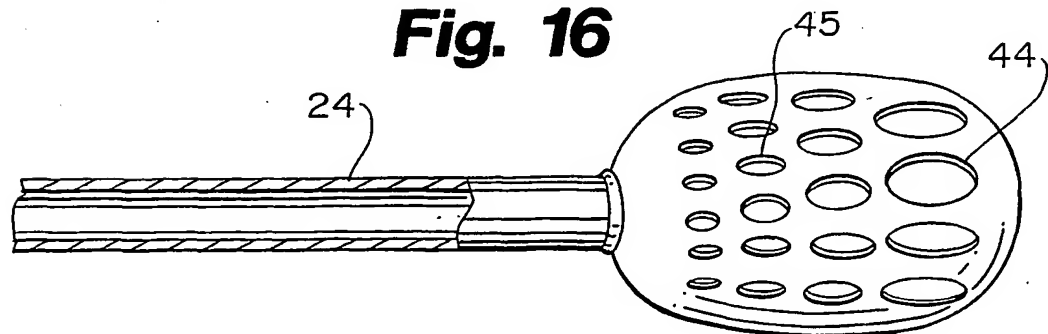
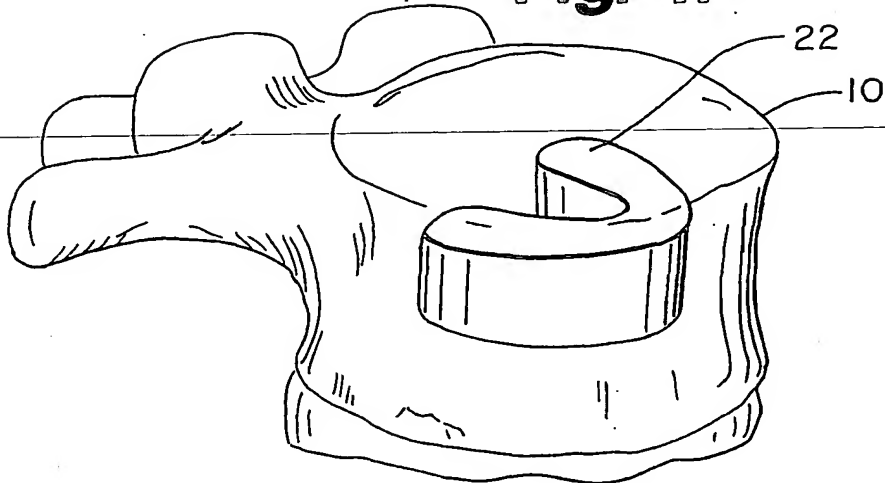
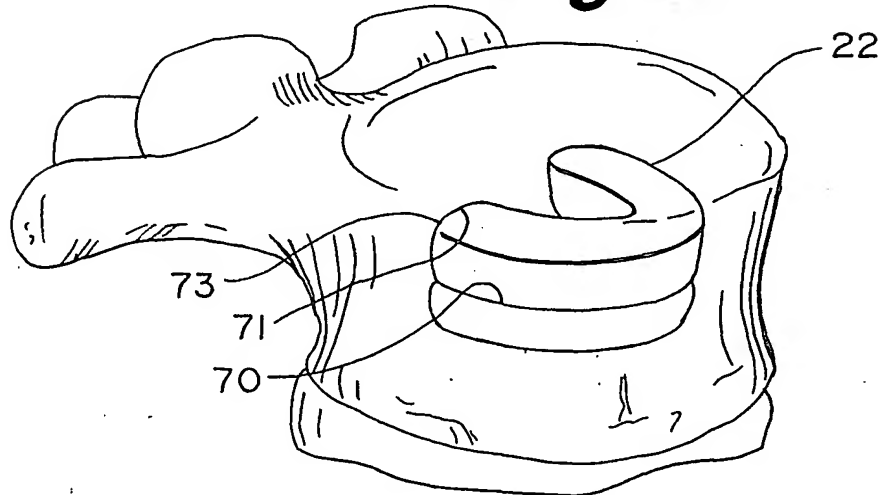
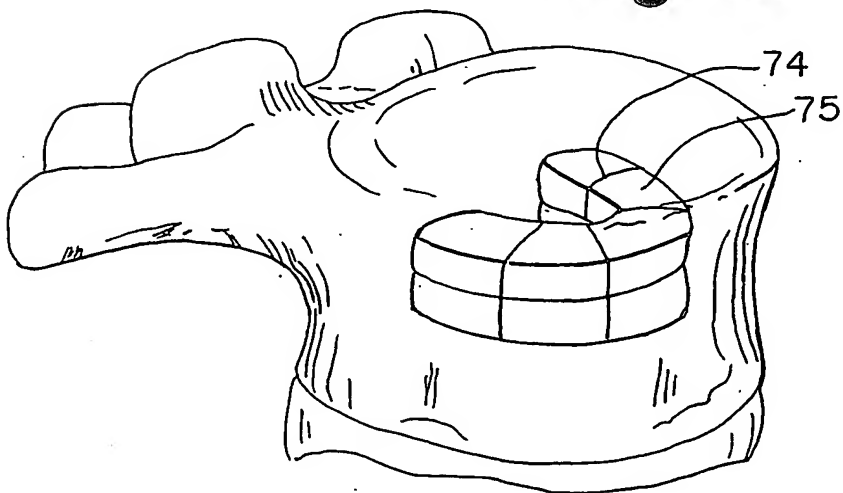


Fig. 13

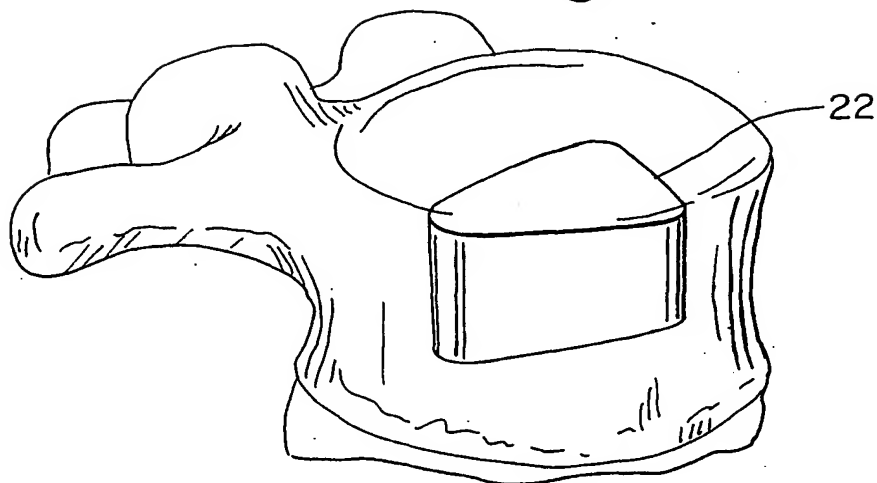
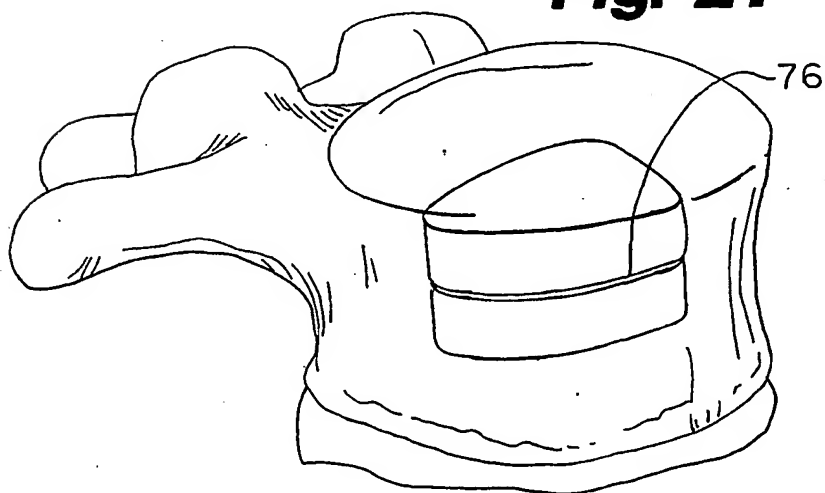
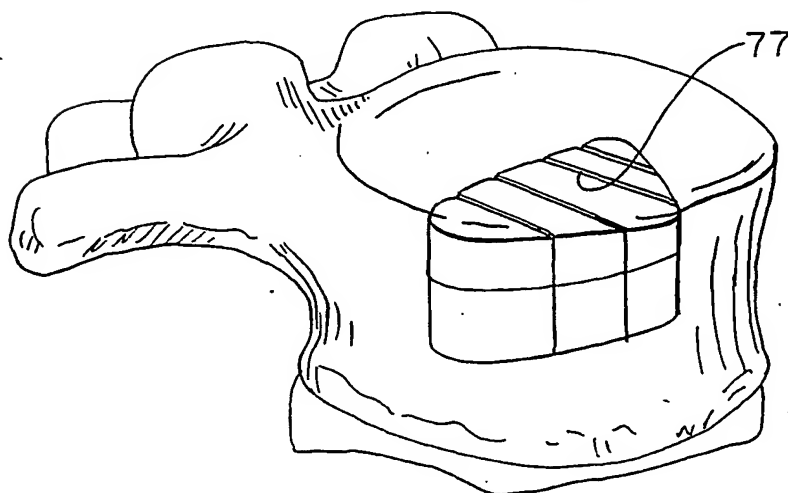


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Fig. 14**Fig. 15****Fig. 16**

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Fig. 17**Fig. 18****Fig. 19**

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Fig. 20**Fig. 21****Fig. 22**

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Fig. 23

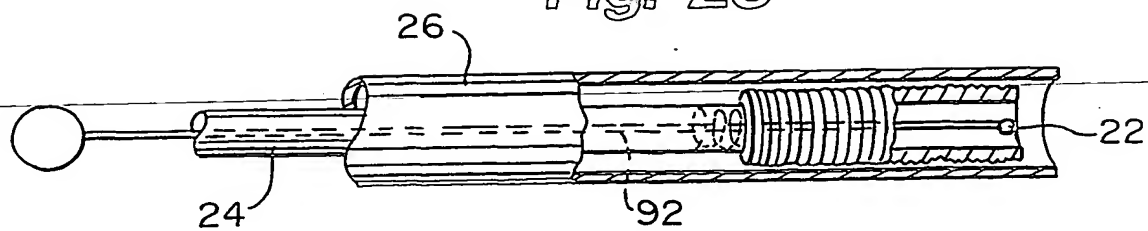
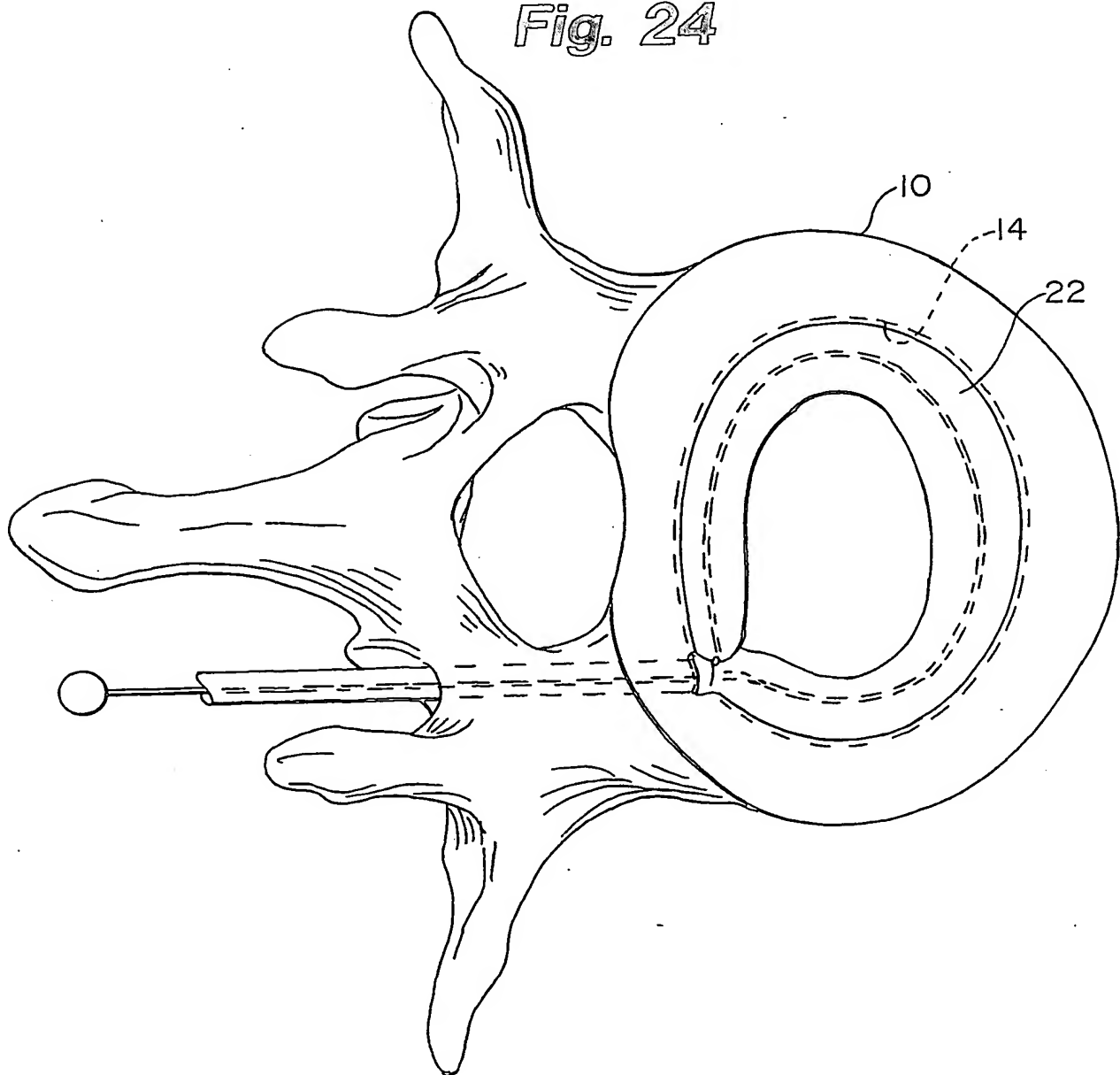
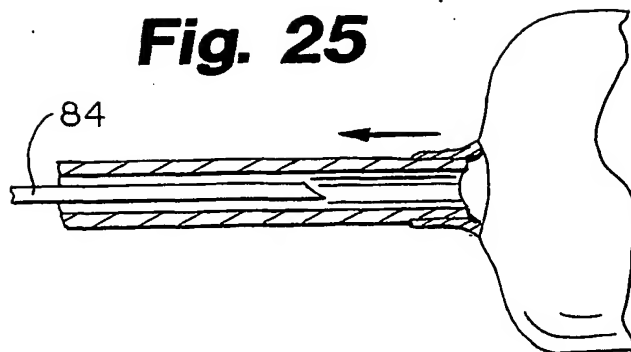
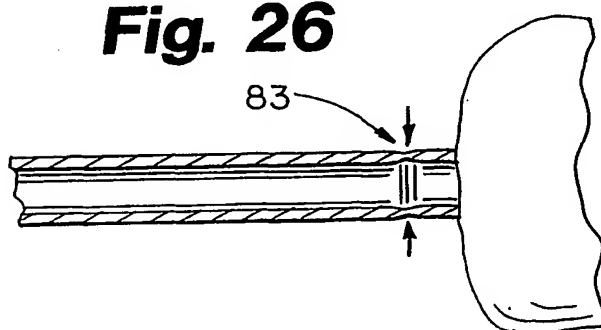
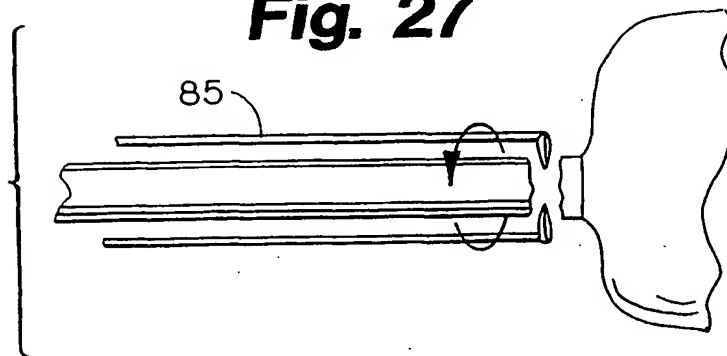
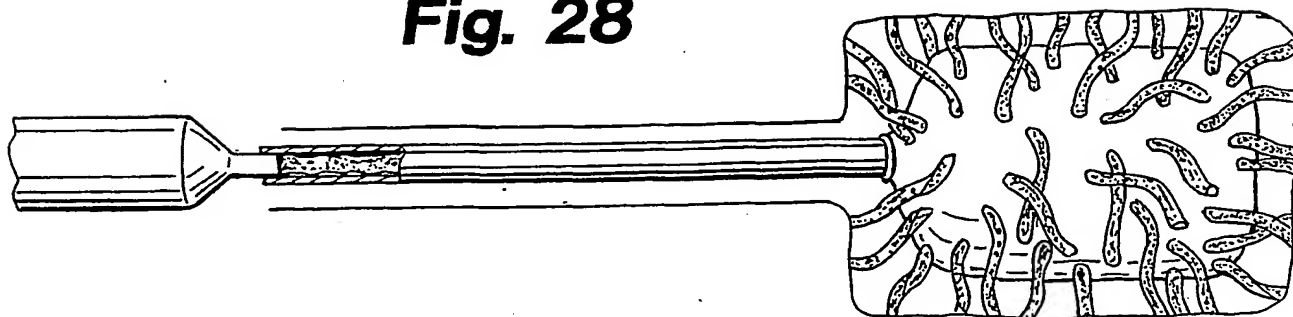


Fig. 24



II/II

Fig. 25**Fig. 26****Fig. 27****Fig. 28**

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/06136

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 2/44

US CL :623/17.12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/17.12,17.11,17.16;606/192

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

search terms: fluid, liquid, membrane, fill tube, vertebrae, spine, elastic

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,716,416 A (Lin) 10 February 1998, Figs. 1B, 4A-E, col. 2, lines 54-57, col. 3, lines 3-8, 10-14.	1-3, 5, 6, 9-13, 16, 18, 19, 25, 26
X	US 5,171,280 A (Baumgartner) 15 December 1992, col. 1, lines 57-60, col. 2, lines 53-55 and col. 3, lines 40-45, col. 4, lines 30-33.	1-3, 5, 7, 12-, 15, 16, 18, 25
X -- Y	US 5,827,289 A (Reiley et al) 27 October 1998, col. 4, line 65, col. 5, lines 4, 23-50, Fig. 4.	1, 2, 4-8, 12, 13, 17-26 --- 14, 27

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

23 APRIL 2001

Date of mailing of the international search report

16 MAY 2001

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INTERNATIONAL SEARCH REPORT

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,961,554 A (Janson et al) 5 October 1999, Figs. 2, 3, 9C, 9E, 9I, col. 3, lines 51-57, col. 5, lines 21-27, 54-55.	1, 2, 6, 11, 12, 13, 15, 25, 26

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